DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 8, 2014

Dräger Medical GmbH
Mr. Ulrich Schröder
Director Regulatory & Clinical Affairs
Moislinger Allee 53-55
23542 Luebeck, Germany

Re: K121886
Trade/Device Name: Savina 300
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: June 10, 2014
Received: June 16, 2014

Dear Mr. Schröder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K121886

Device Name

SAVINA 300

Indications for Use *(Describe)*

Savina 300 is a ventilator intended for the ventilation of adults and pediatric patients starting from 5 kg (11Ibs) bodyweight.
Savina 300 offers mandatory ventilation modes, ventilation modes supporting spontaneous breathing, and airway monitoring.
Savina 300 is intended for the following environments of use:
- In intensive care wards, recovery rooms and generally for hospital use
- During the transport of ventilated patients within the hospital
- During secondary transport from one hospital to another (without trolley, monitor not mounted on Savina 300)
- During transport flights with aircraft (without trolley, monitor is not mounted on Savina 300)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Anya C. Harry -S
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510(k) Summary according to 21 CFR 807.92

Applicants Name and Address:

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23542 Luebeck
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Establishment Registration Number: 9611500

Contact Person:

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Director Regulatory & Clinical Affairs

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Applicants US Contact Person

Beth Zis
Director Regulatory Affairs

Tel. No.: 978 3798 285
Fax No.: 978 3798 335

Date submission was prepared:

June 2012

Device Name:

Trade Name:	Savina 300
Common Name:	Intensive Care Ventilator

Classification:

Class 2

Regulation No.	Device	Product Code
Preferred Code:		
868.5895	Ventilator, continuous, facility use	73CBK
For predicates:		
868.5895	Ventilator, continuous, facility use	73CBK

Reason for the 510(k): Substantial Equivalence

The technological concept of the Savina 300 is equivalent to Savina. The functionality is equivalent to the Infinity Acute Care System Workstation Critical Care and the flight transport indication is equivalent to the Oxylog 3000 Plus.

Legally Marketed Device to which Substantial Equivalence is claimed:

510(k) No.	Trade name	Company
K003068	Savina	Draeger Medical GmbH
K023289	Savina NIV Option	Draeger Medical GmbH
K040642	Savina with LPO	Draeger Medical GmbH
K093633	Infinity Acute Care System Workstation Critical Care	Draeger Medical GmbH
K103625	Oxylog 3000 Plus	Draeger Medical GmbH

Executive Summary

This submission comprises the critical care ventilator **Savina 300** for the ventilation of adult and pediatric patients in intensive care units, in recovery rooms and generally for hospital use. Savina 300 is also intended during the transport of ventilated patients within the hospital, during secondary transport from one hospital to another and during transport flights with fixed-wing aircraft.

Savina 300 is a turbine driven ventilator with a 12.1” color touch screen for easy handling, providing tube and mask based ventilation capabilities. Air is taken from ambient. O2 can be taken from central gas supply, bottle supply (with appropriated accessories) or from another low pressure oxygen source (LPO).

The ventilation unit of the Savina 300 is a microprocessor-controlled ventilator. The Savina 300 provides overpressure ventilation and adjustable oxygen concentration with pressure- and volume-controlled automatic and spontaneous breathing modes.

Savina 300 provides the following ventilation modes:
Volume-controlled ventilation:
• VC-CMV (Volume Control-Continuous Mandatory Ventilation)
• VC-AC (Volume Control-Assist Control)
• VC-SIMV (Volume Control-Synchronized Intermittent Mandatory Ventilation)
• VC-MMV (Volume Control-Mandatory Minute Volume Ventilation)

Pressure-controlled ventilation:
• PC-SIMV+ (Pressure Control – Synchronized Intermittent Mandatory Ventilation plus)
• PC-APRV (Pressure Control - Airway Pressure Release Ventilation)
• PC-AC (Pressure Control - Assist Control)

Support of spontaneous breathing:
• SPN-CPAP (Spontaneous-Continuous Positive Airway Pressure)

Additionally the ventilation unit features special modes to complement the ventilation modes. If breathing of a spontaneously breathing patient stop, Apnea Ventilation switches over automatically to volume-controlled mandatory ventilation.

By switching on the flow trigger, the mandatory strokes are synchronized with the patient's spontaneous breathing attempts.

With AutoFlow, the inspiration flow is decelerated and regulated and thus pressure peaks can be avoided.

The human interface supports simultaneous display of patient waveforms, parameter data, alarm display and annunciation.

The Savina 300 produces visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits. The Savina 300 can interface with specific Dräger Medical therapeutically and diagnostic equipment, as well as third party devices via a MEDIBUS data connection.

Savina 300 provides CO2 measurement as waveform and end tidal CO2 measurement.

Indications for Use:

Savina 300 is a ventilator intended for the ventilation of adults and pediatric patients starting from 5 kg (11lbs) bodyweight.

Savina 300 offers mandatory ventilation modes, ventilation modes supporting spontaneous breathing, and airway monitoring.

Savina 300 is intended for the following environments of use:

- In intensive care wards, recovery rooms and generally for hospital use
- During the transport of ventilated patients within the hospital
- During secondary transport from one hospital to another (without trolley, monitor not mounted on Savina 300)
- During transport flights with aircraft (without trolley, monitor is not mounted on Savina 300)

List of Performance Testing:

Performance complies with the following standards:

Applied external Standards	
IEC 60601-1 : 1988 + A1: 1991 + A2: 1995	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-12: 2001	Medical electrical equipment – Part 2-12: Particular Requirements for the safety of lung ventilators – critical care ventilators
IEC 60601-1-4: 1996 + A1: 1999	Medical Electrical Equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable Electrical Medical Systems
IEC 60601-1-6 : 2006	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard - Usability
IEC 60601-1-8: 2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 14971: 2007, Corrected version 2007-10-01	Medical devices - Application of risk management to medical devices
ISO 17664: 2004	Sterilization of medical devices – information to be provided by the manufacturer for the reprocessing of resterilizable medical devices
IEC 62304: 2006	Medical Device Software – Software Life Cycle Processes

Applied external Standards	
RTCA-DO 160G: 2010 All applicable clauses referring to radiated electromagnetic emissions and mechanical safety	Environment Conditions and Test Procedures for Airborne Equipment
ISO 21647: 2005	Medical electrical equipment – Particular requirements fort he basic safety and essential performance of respiratory gas monitors with Technical Corrigendum
ISO 10993-1: 2009 + Cor. 1: 2010	Biological Evaluation of medical devices – Part 1: Evaluating and testing
FDA Draft Reviewer Guidance for Ventilators: 1995	
ASTM Standard F1100 – 90 (Reapproved 1997)	Standards Specification for Ventilators Intended for Use in Critical Care

Comparison of Technological Characteristics between Savina 300 and Predicates

Specification	Savina 300 SW 4.n	Savina (legally marketed device)	IACS WS CC (legally marketed device)	Oxylog 3000 Plus (legally marketed device)
Manufacturer	Dräger Medical GmbH	Dräger Medical GmbH	Dräger Medical GmbH	Dräger Medical GmbH
US FDA 510(k) number	K121886	K003068 (Savina) K023289 (NIV Option) K040642 (LPO Option)	K093633	K103625
FDA Regulation number	To be assigned	868.5895	868.5895	868.5895
FDA Product code	CBK	CBK	CBK	CBK
FDA Classification	Continuous ventilator, Class 2	Continuous ventilator, Class 2	Continuous ventilator, Class 2	Continuous ventilator, Class 2
Intended use	Savina 300 is a ventilator intended for the ventilation of adults and pediatric patients starting from 5 kg (11 lbs) bodyweight.	Long-term ventilator for intensive care. For patients requiring 50 mL tidal volume upwards.	The Infinity Acute Care System Workstation Critical Care (in the following called IACS WS CC) is intended for the ventilation of adult, pediatric and neonatal patients.	The Oxylog 3000 plus is a time-cycled, volume controlled and pressure controlled emergency and transport ventilator for patients requiring mandatory or assisted ventilation with a tidal volume from 50 mL upwards.
Intended User	Savina 300 is only intended to be used by trained medical personnel	Savina is only intended to be used by trained medical personnel	IACS WS CC is only intended to be used by trained medical personnel	Oxylog 3000 plus is only intended to be used by trained medical personnel

Specification	Savina 300 SW 4.n	Savina (legally marketed device)	IACS WS CC (legally marketed device)	Oxylog 3000 Plus (legally marketed device)
Environment of use	Savina 300 is intended for the following environments of use: – In intensive care wards, in recovery rooms and generally for hospital use – During the transport of ventilated patients within the hospital – During secondary transport from one hospital to another (without trolley, monitor not mounted on Savina 300) – During transport flights with aircraft (without trolley, monitor not mounted on Savina 300)	– In the Intensive Care ward, in the recovery room and generally for hospital use. – During transfer of ventilated patients within the hospital. – During secondary transport from one hospital to another.	Suitable for stationary use in hospitals or hospital-like facilities or for intrahospital patient transport. Not intended for use in: – In hyperbaric chambers – For magnetic resonance imaging (MRT, NMR, NMI) – With flammable gases or anesthetic agents – In areas with combustible or explosive substances – In rooms without adequate ventilation	- Mobile use for emergency patients, in both outdoor and indoor environments. - During transport in ambulances or aircraft, including helicopters. - In accident and emergency departments. - When moving ventilated patients around the hospital. - In the recovery room.
Modes of ventilation	Volume-controlled ventilation: VC-CMV VC-AC VC-SIMV VC-MMV	Volume-controlled ventilation: IPPV IPPV Assist SIMV	Volume-controlled ventilation: VC-CMV VC-AC VC-SIMV VC-MMV	Volume-controlled ventilation: VC-CMV VC-AC VC-SIMV/PS
	Pressure-controlled ventilation: PC-AC, PC-SIMV+ PC-APRV	Pressure-controlled ventilation: SIMV+	Pressure-controlled ventilation: PC-AC PC-SIMV+ PC-APRV	Pressure-controlled ventilation: PC-SIMV+
	Support of spontaneous breathing: SPN-CPAP/PS	Support of spontaneous breathing: CPAP/ASB	Support of spontaneous breathing: SPN-CPAP/PS SPN-CPAP/VS SPN-PPS	Support of spontaneous breathing: SPN-CPAP SPN-CPAP/PS
Non Invasive Ventilation	√	√	√	√
Pressure Limited Ventilation (PLV)	Optional in VC modes without AF	Optional with IPPV, SIMV, SIMV/ASB	Optional in VC modes without AF	-
Apnea Ventilation	Optional with VC-SIMV, SPC-CPAP	Optional with SIMV, SIMV/ASB, CPAP/PS	Optional with PC-SIMV, PC-BIPAP, VC-MMV, VC-SIMV, SPN-PPS, SPN-CPAP, SPN-CPAP/VS	Optional with SpnCPAP
Pressure Support (PS) (Assisted Spontaneous Breathing) (ASB))	Oprional with SPN-CPAP, PC-BIPAP, VC-SIMV	Optional with CPAP, BIPAP, SIMV	Optional with PC-SIMV, VC-SIMV, PC-BIPAP, SPN-CPAP, VC-MMV, Var. PS	Optional with VC-SIMV, PC-SIMV+, SpnCPAP
Flow trigger	√	√	√	√
Intrinsic PEEP	Optional	--	Optional	--
Inspiratory termination criterion	√	--	√	--
Sigh	Optional: 2 strokes / 3 min	Optional: 2 strokes / 3 min	Optional: variable	
AutoFlow	(optional) with VC-CMV, VC-AC, VC-SIMV, VC-MMV	(optional) with IPPV, SIMV	(optional) with VC-CMV, VC-SIMV, VC-MMV, VC-AC	(optional) with VC-CMV, VC-AC, VC-SIMV
Special procedures:	– Man. insp./hold	– Insp./hold	--	– Insp./hold
	– Exp. Hold.	--	– Exp. Hold.	--
Medication nebulization	optional	optional	optional	--
O2 suction	√	√	√	--
Therapy types	– Invasive ventilation (Tube)	--	– Invasive ventilation (Tube)	--
Monitoring sensors:				
Flow sensor	√	√	√	--
Pressure sensor	√	√	√	--

Specification	Savina 300 SW 4.n	Savina (legally marketed device)	IACS WS CC (legally marketed device)	Oxylog 3000 Plus (legally marketed device)
O2 sensor	√	√	√	--
Proximal temperature sensor	√	√	--	--
CO2 sensor	√ (optional)	--	√	√
Ventilation and Device Monitoring:				
Airway pressure, PAW	√	√	√	√
Expiratory minute volume, MV	√	√	√	√
Inspiratory tidal volume, VTi	√	√	√	--
Inspiratory O2 concentration, FiO2	√	√	√	--
End-expiratory CO2 concentration, etCO2	√ (optional)	--	√ (optional)	√
Apnoe time, TApnoe	√	√	√	--
Respiratory rate, fspn	√	√	√	√
Logistic alarms (power-, gas supply failure), machine malfunction	√	√	√	√
Displays	– Curves; three at a time	--	– Curves; four at a time	– Curve
	– Numeric parameters	– Numeric parameters	– Numeric parameters	– Numeric parameters
	– Lists for measured values and set values	--	– Lists for measured values and set values	--
	Graphic trends	--	Graphic trends	--
	Numeric trends	--	Numeric trends	--
	Loops	--	Loops	--
	Logbook	--	Logbook	--
Control principle	time-cycled, volume-constant, pressure-controlled	time-cycled, volume-constant, pressure-controlled	time-cycled, volume-constant, pressure-controlled	time-cycled, volume-constant, pressure-controlled
Software controlled device	Yes	Yes	Yes	Yes
Display and control unit				
Screen size	12,1“	--	17”	--
Touchscreen	√	--	√	
✓ Operating elements	• Large color screen with information and controls needed for adjustment and control of ventilation therapy. • Function softkeys on the screen for rapid access and selection of major functions. • Central rotary knob for adjustment and confirming settings on the screen. • 6 hard keys for essential maneuvers and Alarm reset / Audio paused	--	• Large color screen with information and controls needed for adjustment and control of ventilation therapy. • Function softkeys on the screen for rapid access and selection of major functions. • Central rotary knob for adjustment and confirming settings on the screen. • 1 hard keys for audio paused	--
Environmental Conditions				
During operation				
Temperature	5 to 40 °C (41 to 104 °F)	10 to 40 °C (50 to 104 °F)	10 to 40 °C (50 to 104 °F)	-20 to 50 °C (-4 to 122 °F)
Atmospheric pressure	700 to 1060 hPa (10.20 to 15.30 psi)	700 to 1060 hPa (10.20 to 15.30 psi)	700 to 1060 hPa (10.20 to 15.30 psi)	570 to 1200 hPa (8.27 to 17.40 psi)
Relative humidity	5 to 90 % without condensation	5 to 90 % without condensation	5 to 90 % without condensation	5 to 95% without condensation
During operation with expiratory filter MP01781				
Temperature	10 to 40 °C (50 to 104 °F)	10 to 40 °C (50 to 104 °F)	10 to 40 °C (50 to 104 °F)	--

Specification	Savina 300 SW 4.n	Savina (legally marketed device)	IACS WS CC (legally marketed device)	Oxylog 3000 Plus (legally marketed device)
Atmospheric pressure	700 to 1060 hPa (10.20 to 15.30 psi)	700 to 1060 hPa (10.20 to 15.30 psi)	700 to 1060 hPa (10.20 to 15.30 psi)	--
Relative humidity	10 to 90 % without condensation	5 to 90 % without condensation	5 to 90 % without condensation	--
During storage and transportation				
Temperature	–20 to 60 °C (–4 to 140 °F)	–20 to 70 °C (–4 to 158 °F)	–20 to 60 °C (–4 to 140 °F) without PS500 -15 to 40 °C (5 to 104 °F) with PS500	–40 to 75 °C (–40 to 167 °F)
Atmospheric pressure	600 to 1200 hPa (8.7 to 17.40 psi)	600 to 1200 hPa (8.70 to 17.40 psi)	500 to 1060 hPa (7.25 to 15.37 psi)	570 to 1200 hPa (8.27 to 17.40 psi)
Relative humidity	10 to 95 % without condensation	10 to 95 % without condensation	5 to 95 % without condensation	5 to 95% without condensation
Operating Data Mains power supply				
Mains power connection	100 V to 240 V, 50/60 Hz	100 V to 240 V, 50/60 Hz	100 V to 240 V, 50/60 Hz	100 V to 240 V, 50/ 60 Hz
Current consumption				2.6 A (-4 to 104 °F) / 1.3 A (104° to 122 °F)
At 230 V	max. 1.3 A	max. 1.1 A	max. 0.8 A Ventilation Unit with Medical Cockpit	--
At 100 V	max. 3.4 A	max. 3.4 A	max. 1.8 A Ventilation Unit with Medical Cockpit	--
Protection Class				
Temp.Sensor AWT01 (sensor connected)	Type BF	Type BF	Type BF	Type BF
Expiratory valve and breathing hoses	Type BF	Type BF	Type BF	Type BF
CO2 sensor (sensor fitted)	Type BF	--	Type BF	Type BF
Internal battery				
Type	Lead-acid gel batteries, sealed, maintenance-free	Lead-acid gel batteries, sealed, maintenance-free	NiMH battery, sealed, maintenance-free	Lithium ion battery
Capacity	3.5 Ah	3.5Ah	2.5 Ah	2.4 Ah
Voltage	24 V	24 V	24 V	19 V
Time bridged following a mains power failure with new and fully charged internal battery	typ. 45 min	min. 30 minutes (typically 40 minutes)	min. 30 minutes	4 hours
Gas supply				
O2 gauge pressure	3 bar (43.5 psi) –10 % to 6.0 bar (87 psi)	3 bar (43.5 psi) –10 % to 6.0 bar (87 psi)	--	--
O2 peak input flow	180 L/min (at 2.8 bar input pressure)	180 L/min (at 2.8 bar input pressure)	130 L/min (at 2.8 bar (40.6 psi) input pressure) 180 L/min (at 4.0 bar (58.0 psi) input pressure)	--
Dew point	5 °C (41 °F) below ambient temperature	5 °C (41 °F) below ambient temperature	5 °C (41 °F) below ambient temperature	--
Oil concentration	<0.1 mg/m3	<0.1 mg/m3	<0.1 mg/m3	--
Particle size	Dust-free air (filtered with filter size <1 µm)	Dust-free air (filtered with filter size <1 µm)	Dust-free air (filtered with filter size <1 µm)	--
Gas consumption				
Output for ventilation	Depends on ventilation settings	Depends on ventilation settings	Depends on ventilation settings	--
Output for pneum. Medicament nebuliser	Medical air or O2 max. 2.0 bar (or 210 kPa or 30.5 psi), max. 10 L/min	Medical air or O2 max. 2.0 bar (29 psi), max. 10 L/min	Medical air or O2 max. 2.1 bar (210 kPa or 30.5 psi), max. 11 L/min	--
Automatic gas switch-over	n.a.	n.a.	If one gas fails, the device switches over to the other gas	--

Conclusion:

The intended use and the functionalities as the predicate devices remain the same. The function and the principle of operation as well as the characteristics are equal. In summary, the Savina 300 described in this submission is substantially equivalent to the predicate devices.